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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,978	07/30/2003	Dennis McDevitt	022956-0234	9506
21125	7590	12/03/2004	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,978

Applicant(s)

MCDEVITT ET AL.

Examiner

Peter J Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30,32-40 and 42-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30,32-40 and 42-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

There are **10** independent claims in this application.

Claims 1-27 have been cancelled.

Claims 28-30, 32-40, and 42-71 are pending.

The instant action is a continuation of USPN 6,660,023, which is a continuation of USPN 6,527,794.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 51 and 56 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office requests clarification toward this claim in a future response as to the meaning of "opposed open ends".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 47, 48, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce.

Independent claims

47, 48, 49

Pierce makes obvious a device for anchoring a filament to tissue or bone, comprising:

an anchor member (elements 14 and 15 combined) adapted to be embedded in bone, the anchor having at least one cavity (4) therein and including first (15) and second (14) components adapted to hold a filament by interference fit (depicted in figure 20).

Dependent claims

51. The device of claim 49, wherein the at least one cavity includes opposed open ends (4). The Office requests clarification toward this claim in a future response as to the meaning of "opposed open ends".

Claims 47-49 all contain language regarding movement of filament, breaking strengths of filament, etc. which are related to the size and strength of the chosen filament. The Office contends that to arrive at the Applicant's disclosed invention one would merely have to perform routine experimentation to determine the corresponding filament size

and strength. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Pierce in light of routine experimentation. The **motivation** would be to design a suture anchor that was able to hold sutures in place as desired.

3. **Claims 28-30, 32-40, 42-46, 50, and 52-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (5,324,308) in view of Le et al. (Re. 36,289).**

Independent claims

28, 38, 52, 57, 58, 64, 68

Pierce in view of Le et al. (Le) makes obvious a device for anchoring a filament to tissue or bone, comprising: [Note: all parentheticals refer to Pierce unless stated otherwise]

an anchor member or element or first component (15) adapted to be embedded in bone and having a cavity (4B) formed therein;

an insertion element or stem or second component (14) **with a frangible portion** (Le, 212, figure 19) attached to an elongate shaft (C) adapted to be disposed in the cavity in the anchor member to retain a filament (B) between the insertion stem (14) and the anchoring element (15); at least one radial channel (serrated edges equivalent to channels, see 2 in figures 4 and 19) formed around a head of the insertion element; and at least one suture-receiving channel formed in the insertion element and adapted to seat a filament, the suture-receiving channel (3) having a size adapted to substantially secure the filament by compression/interference fit (depicted in figure 20; B rests

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between elements 14 and 15; the larger the chosen suture B, the greater the compression fit) therein when the insertion element is disposed in the cavity in the member (the Office contends that the distal section of element 14 in figure 19 is disposed on its left hand side in the cavity 4 of element 15).

Dependent claims

29. The device of claim 28, where the at least one suture-receiving channel (3) is formed on a surface of the insertion element (see figure 17).

30. The device of claim 29, where the at least one suture-receiving channel (3) extends between proximal and distal ends of the insertion element (see figure 17).

31. The device of claim 29, further comprising at least one radial channel (see 2 in figure 19) formed around a head of the insertion element (14).

32, 39. The device of claim 29, wherein the cavity (4B) comprises a lumen extending between proximal and distal ends of the anchor member/element (see figure 14).

33. The device of claim 29, further comprising at least one filament (B) disposed within the at least one suture-receiving channel (3, see figure 20).

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34. The device of claim 33, wherein the filament is non-movable when the insertion element is disposed in the cavity in the anchor member. This is a matter of size of the filament chosen, which would be determined through routine experimentation and therefore is deemed obvious by Pierce in view of Le.

35. 44. The device of claim 29 (38), wherein the anchor member is adapted to be embedded in a tunnel in bone (E, F, figure 28).

36. 45. The device of claim 29 (38), wherein the insertion element or stem (14) has an outer diameter that is greater than an inner diameter of the cavity in the anchor member or element (4).

37. 46. The device of claim 28 (38), wherein the device is formed from a biocompatible material selected from the group consisting of polyethylene, polypropylene, steel, poly-L-lactide and lactide-glycolide compositions. **Le mentions these materials in col. 7:21-31.**

40. The device of claim 39, where the insertion stem (14) includes at least one suture-receiving channel (3) that extends between proximal and distal ends thereof (15).

42. 62. The device of claim 39 (58), further comprising at least one filament (B) disposed within the at least one suture-receiving channel.

43. 63. The device of claim 42 (58) wherein the filament is non-movable "interference fit" when the insertion stem is disposed in the cavity in the anchoring element. This is a matter of size of the filament chosen, which would be determined through routine experimentation and therefore is deemed obvious by Pierce in view of Le.

50. 55. 60. 61. The device of claim 49 (52) (59) (58), wherein the anchor member includes a frangible portion (**Le, 212, figure 19**) and an elongate deployment member or shaft (**Le 211**) that is adapted to shear during deployment of the device into bone.
Note: Le 211 is analogous to C and D in Pierce.

53. The device of claim 52, wherein the first and second components are adapted to hold the filament such that, where the filament has a breaking strength greater than the threshold force, the filament is substantially non-movable in response to a tensional force less than a threshold force applied to at least one portion of the filament, and the filament is longitudinally movable in response to a tensional force greater than the threshold force applied to the at least one portion of the filament. This is a matter of strength of the filament chosen, which would be determined through routine experimentation and therefore is deemed obvious by Pierce in view of Le.

54. The device of claim 52, wherein the first and second components are adapted to hold the filament such that the filament is effective to resist operational forces to which

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the filament is subjected to subsequent deployment of the device in a patient's body.

This is a matter of size of the filament chosen, which would be determined through routine experimentation and therefore is deemed obvious by Pierce in view of Le.

56. The device of claim 52, wherein the at least one cavity component includes opposed open ends (4). The Office requests clarification toward this claim in a future response as to the meaning of "opposed open ends".

59. The device of claim 58, wherein the second component (14) includes a flange (2, figure 5) formed on a terminal end thereof, the flange having an outer diameter that is greater than an inner diameter of the cavity (4) in the first component (15).

65. 69. The device of claim 65 (68), wherein the second component (14) includes a flange (protruding rim between elements 3 in figure 7) formed on a terminal end thereof and adapted to abut a terminal end of the first component (15) ("flange" abuts 15 in figure 20).

66. 67. The device of claim 65 (64), wherein the flange is formed near a distal end of the second component (14), and a proximal end of the second component (15) is frangibly attached to the elongate shaft (this is found in the supporting reference Le, figure 19, elements 211, 212 as discussed *supra*.)

70. 71. The device of 68 (70), wherein the anchoring element (15) includes a cavity (the entire angled top half of 15 including elements 10 and 7) for receiving the insertion element (14) (see figure 19), and further comprising a filament (B) extending through the cavity between the anchoring element and the insertion element. Note: the cavity here (the entire angled top half of 15 including elements 10 and 7) and the cavity (4) mentioned *supra* are not the same element.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Pierce in view of Le by including a frangible portion into the design of Pierce. The **motivation** would be to easily remove the elongate shaft used to insert the Pierce anchor (analogously to the jaws D disclosed by Pierce).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bonutti ('073), DiPoto ('953), Johnson ('844), Anspach, Jr. ('695), McDevitt ('963), Fenton, Jr. ('751), Beyar ('700).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
November 9, 2004



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